EXHIBIT 1012

JAN 19 2005

K042961

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510(k) Summary

Common Name:	Fluorescent Angiographic System
Classification:	21 CFR 892.1600
Manufacturer:	Novadaq Technologies Inc. 2585 Skymark Avenue Suite 306 Mississauga, Ontario Canada L4W 4L5 905.629.3822
Contact Name:	Rick Mangat Vice President - Cardiac

Legally Marketed Predicate Devices:

The Novadaq SPY™ Intra-operative Imaging System: SP2000 is equivalent to two predicate devices.

The Philips Integra Series 2 Systems (K984545) is an Angiographic X-Ray System intended for use in acquiring diagnostic quality images during cardiac, angiographic, vascular, neurovascular, and interventional applications.

The Heidelberg Retinal Angiographic System (K944261) is also equivalent to the SPY™ system. The indication for use is to acquire images of the posterior segment of the eye and to analyze these images quantitatively for diagnostic purposes.

Device Description:

The SPY™ Intra-operative Imaging System: SP2000 is indicated for use for intra-operative visual assessment of the coronary vasculature and grafts during CABG surgery.

The SPY™ system provides the surgeon with the capability to view, record and replay fluorescent images of blood vessels and bypass grafts of the heart. A laser light source is used to illuminate the heart surface. Indocyanine Green (ICG) is injected intravenously through the central venous line, bypass pump or cardioplegia line and, while coursing through the coronary arteries and grafts, the absorption of laser light causes excitation of the dye followed by emission of infrared energy. The result is a fluorescent image of the coronary vasculature. A CCD camera captures the image. These images are used to evaluate the integrity of the coronary vasculature and bypass grafts.

Testing:

Animal studies, human experience and in vitro testing were conducted to support the safe and effective use of the SPY™ system.

In Vitro Testing:

Testing of the SPY™ system was completed in conformance with the following standards. The SPY™ system successfully met all of the requirements for these standards.

1. Electrical per IEC 60601-1 and UL2601-1
2. Electromagnetic Compatibility per IEC 60601-1-2
3. Light Emitting Laser Products per 21 CFR 1040
4. Safe Use of Lasers in Health Care Facilities per ANSI Z136.3
5. American National Standard for Safe Use of Lasers per ANSI Z136.1

In Vivo Testing:

Animal studies and human experience in 950 CABG procedures were completed to demonstrate safety and effectiveness.

1. The exposure for the SPY™ system is 35 mW/cm^2 which is far below the MPE of 327 mW/cm^2 established by ANSI for exposure to the skin.
2. Use of the SPY™ system does not cause any thermal damage to the heart tissue.
3. There were no changes to the electrocardiograms or arterial pressures during and following SPY™ use.
4. There were no acute or long-term cellular effects of using the SPY™ system.
5. There were no acute or long-term renal or hepatic effects of using the SPY™ system.
6. The image quality of the SPY™ system was equivalent to radiographic angiography.
7. The SPY™ system was able to acquire excellent images of the entire vascular bed on each aspect of the heart.

Conclusions:

The above testing demonstrates that the SPY™ Intra-operative Imaging System is safe and effective in imaging the coronary vasculature and bypass grafts intra-operatively and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

Novadaq Technologies Inc.
c/o Mr. Rick Mangat
Vice President - Cardiac
2585 Skymark Avenue, Suite 306
Mississauga, Ontario
Canada L4W 4L5

Re: K042961
Trade Name: SPY™ Intra-operative Imaging System: SP2000
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: II (two)
Product Code: IZI
Dated: November 23, 2004
Received: November 24, 2004

Dear Mr. Mangat:

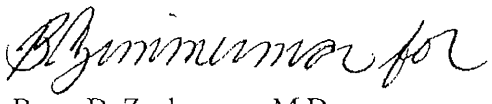
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
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Center for Devices and
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Enclosure

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